

Iovate Health Sciences U.S.A. Inc.
3880 Jeffrey Boulevard,
Blasdell, NY 14219

905.678.4052
Fax 905.678.6590
www.iovate.com



1039 5 OCT 28 P2-20

OCT 19 2005

Oct 17, 2005

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

NOTIFICATION OF STATEMENT OF NUTRITIONAL SUPPORT

Dear Sir or Madam:

In accordance with Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, and pursuant to 21 C.F.R. § 101.93, we hereby provide the following notice with regard to the marketing of the Dietary Supplement described below:

Distributor: Iovate Health Sciences U.S.A. Inc., 3880 Jeffrey Blvd., Blasdell, NY 14219

Name of Supplement: GAKIC®

Statement of Nutritional Support:

Advanced Muscle Fatigue Toxin Reducer

Immediate 10.5% increase in strength

Increase fatigue resistance by up to 28%

More explosive reps and performance now

The GAKIC Advantage

GAKIC® is an advanced new supplement complex that has been scientifically proven to cause immediate and significant increases in strength and endurance! The effect starts immediately and lasts throughout your workout, lasting long enough to power you through your hardest workouts, or to help you perform better than ever during any sporting event such as football, baseball, basketball, running or other sports. GAKIC is unlike anything you have ever tried – it represents a new scientific development in the creation of an advanced muscle-performance formula. Because of GAKIC's ability to sustain greater muscular power, it allows you to complete more explosive reps during your sets. When taken within minutes of an intense workout, GAKIC's effects can be felt right away throughout the exercise or sporting activity. This strength increase leads to greater workout intensity and muscle stimulation.

The Formula

Developed by researchers at the University of Florida, GAKIC has been engineered to work quickly after dosing at the muscle fiber level, without the need for stimulants. Research suggests that one of the mechanisms likely responsible for the performance-enhancing effects of GAKIC is the removal of the fatigue toxin ammonia, which generally limits muscular power output. With decreased fatigue toxin levels, athletes can perform more muscle work. Powered with Nanomill™ Technology, GAKIC is a novel formula with powerful effects. Working at the muscle fiber level via totally different metabolic mechanisms than creatine, GAKIC should be an addition to any serious athlete's pre-workout regimen. Only Team MuscleTech can bring you GAKIC – the next generation in workout enhancement.

The Science

Using GAKIC before starting your workout produces a 10.5% increase in strength within minutes of dosing and effects lasting throughout your workout or other sporting activities. Even more, GAKIC increases your resistance to fatigue by up to 28%. Researchers know this, because in one clinical study comparing GAKIC use to results seen when using a placebo, GAKIC supplementation significantly increased the total muscle work performed during intense sets of resistance training by an average of 10.5% and improved muscle fatigue resistance by up to 28%. To the best of my knowledge, the information contained in this notice is complete and accurate, and Iovate Health Sciences USA Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,

Shan Chaudhuri
Regulatory Affairs Manager

975 0162 LET

16892

2005-7214